FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Pulmonary-Allergy Drugs Advisory Committee (PADAC)

FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), Silver Spring, MD

January 29, 2013

DRAFT AGENDA

The committee will discuss the New Drug Application (NDA) for olodaterol, sponsored by Boehringer Ingelheim, for the long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. .

8:00 a.m.	Call to Order Introduction of Committee	Chairperson, Pulmonary-Allergy Drugs Advisory Committee (PADAC)
8:05 a.m.	Conflict of Interest Statement	**Cindy Hong, PharmD** Designated Federal Officer, PADAC
8:10 a.m.	Opening Remarks	**Theresa Michele, MD** Clinical Team Leader, Division of Pulmonary, Allergy, and Rheumatology Products (DPARP), Office of Drug Evaluation II (ODE-II), Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**Sponsor Presentations**	**Boehringer Ingelheim**
	Introduction	**Sabine Luik, MD** Head of US Medicine and Regulatory Affairs Boehringer Ingelheim
	COPD Disease Background	**Richard Casaburi, MD, PhD** Professor of Medicine UCLA School of Medicine Medical Director, Rehabilitation Clinical Trials Center Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center
	Olodaterol Clinical Program	**Alan Hamilton, PhD** Senior Clinical Program Leader Boehringer Ingelheim
	Safety and Risk Management of Olodaterol for COPD	**Bernd Disse, MD, PhD** Head, Therapeutic Area Respiratory Diseases Boehringer Ingelheim
	Clinical Summary and Perspective on the Use of Olodaterol for Patients with COPD	**Richard Casaburi, MD, PhD**

DRAFT

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Pulmonary-Allergy Drugs Advisory Committee (PADAC)

January 29, 2013

DRAFT AGENDA (cont.)

9:45 a.m.	Clarifying Questions to the Presenters	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA Presentations**	
	Overview of the Clinical Program	**Robert Lim, MD** Clinical Reviewer DPARP, ODE-II, CDER, FDA
	Statistical Review of Efficacy	**Robert Abugov, PhD** Statistical Reviewer Division of Biostatistics II (DB-II) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Clinical Review of Efficacy, Safety, Risk/Benefit	**Robert Lim, MD**
11:45 a.m.	Clarifying Questions to the Presenters	
12:00 noon.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	**Theresa Michele, M.D.**
2:10 p.m.	Questions to the Committee and Committee Discussion	
3:00 p.m.	**BREAK**	
3:15 p.m.	Questions to the Committee and Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	

DRAFT